

104TH CONGRESS
2D SESSION

H. R. 3065

To amend the Federal Food, Drug, and Cosmetic Act to revise the review of radiopharmaceuticals under section 505 of such Act.

IN THE HOUSE OF REPRESENTATIVES

MARCH 12, 1996

Mr. COBURN (for himself, Mr. BURR, Mr. STUPAK, and Mrs. LINCOLN) introduced the following bill; which was referred to the Committee on Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to revise the review of radiopharmaceuticals under section 505 of such Act.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE AND REFERENCE.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Radiopharmaceutical Review Improvement Act of 1996”.

6 (b) REFERENCE.—Whenever in this Act an amend-
7 ment or repeal is expressed in terms of an amendment
8 to a section or other provision, the reference shall be con-
9 sidered to be made to a section or other provision of the

1 Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 et
2 seq.)

3 **SEC. 2. REVIEW OF RADIOPHARMACEUTICALS.**

4 (a) SEC. 505.—Section 505 (21 U.S.C. 355) is
5 amended by adding the following new subsection at the
6 end thereof:

7 “(n)(1) For purposes of this section, the safety and
8 effectiveness of a radiopharmaceutical are to be deter-
9 mined—

10 “(A) weighing the probable benefit to health
11 from the use of the radiopharmaceutical against any
12 probable risk of injury or illness from such use;

13 “(B) taking into account the absence or pres-
14 ence of pharmacological and toxicological activity of
15 the radiopharmaceutical and the estimated absorbed
16 dose of the radiopharmaceutical.

17 “(2) In the case of a radiopharmaceutical intended
18 to be used for diagnostic purposes, the indications for
19 which such a radiopharmaceutical is approved under this
20 section may refer to processes (such as biochemical, phys-
21 iological, anatomical, or pathological), processes common
22 to or present in one or more disease states, or may refer
23 to a diagnostic procedure used in the diagnosis of one or
24 more diseases.

1 “(3) As used in this subsection and section 503, the
2 term ‘radiopharmaceutical’ means—

3 “(A) an article that is intended for use in vivo
4 in the diagnosis, cure, mitigation, treatment, or pre-
5 vention of disease or a manifestation of disease in
6 men, and that exerts its primary effect by the spon-
7 taneous disintegration of unstable nuclei with the
8 emission of ionizing radiation; or

9 “(B) a reagent kit or nuclide generator that is
10 intended to be used in the preparation of any such
11 article.”.

12 (b) SEC. 503.—Section 503(g)(1) (21 U.S.C.
13 353(g)(1)) is amended—

14 (1) in subparagraph (B), by striking “or”;

15 (2) in subparagraph (C), by striking the period
16 and inserting “; or”; and

17 (3) by inserting after subparagraph (C) the fol-
18 lowing new subparagraph:

19 “(D) a radiopharmaceutical, the persons
20 charged with premarket review of the
21 radiopharmaceutical products shall have pri-
22 mary jurisdiction.”.

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